



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 7 2006

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Edward John Allera
Buchanan Ingersoll PC
1776 K Street, N.W.
Suite 800
Washington, D.C. 20006-2365

Re: Docket No. 2005P-0493/CP1

Dear Mr. Allera,

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on behalf of Breckenridge Pharmaceutical, Inc., and received by the Agency on December 15, 2005. Your petition requests that we establish criteria, analogous to the criteria for marketing Category I drug products under the over-the-counter drug review, that would permit state boards of pharmacy, pharmacy and therapeutics committees, private insurers, and information services to determine the substitutability of prescription hyoscyamine drug products under state pharmacy law to reduce their drug costs with the input of FDA.

We have been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2005P-0493

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